HFI-35 12/11/96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 27 1996

WARNING LETTER

Ref:OC:I1-1741

via FEDERAL EXPRESS

Mr. Andrew F. DeSimone
Imaginative Optics
161 Elliott St., Suite 816
Beverly, Massachusetts 01915

Dear Mr. DeSimone:

This letter is to advise you of items of noncompliance with the Federal laser performance standard encountered during review of the product report submitted for the model I/O 104 rev. A Ablation Laser.

1. 21 CFR 1040.10(g)(2)(iii). Labeling requirements. The product failed to have a warning logotype label as required by this paragraph. Since the unit emits radiation at wavelengths varying from 400 to 700 nm and different than that emitted by the pump laser, the warning logotype on the pump laser cannot be used for compliance with this requirement. The Ablation Laser must have the correct warning logotype label specified in the standard. This label must include the appropriate information for the output of the laser.

2. 21 CFR 1040.10(h)(1)(iii). Information requirements. A reproduction of the correct warning logotype was not in the Product Manual as required by this paragraph. The corresponding location of this label on the product is also to be included in the manual.

3. 21 CFR 1040.10(h)(1)(iv). Information requirements. The statement, "Caution - use of controls ... " was not included in the Product manual as required by this paragraph.

4. 21 CFR 1010.3. Identification. The identification label failed to include the month and year of manufacture as required by this paragraph.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any

manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

    a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to

purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Boston District Office, Food and Drug Administration, One Monument Avenue, Stoneham, MA 02180. If you have further questions on these requirements, please contact Frank W. Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

M Lodya Rodriguez for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health